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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,592	08/24/2001	Yoshihide Hayashizaki	2870-0173P	3624

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,592	HAYASHIZAKI, YOSHIHIDE	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-25,27-40,42-86,89 and 90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-6,8-25,27-40,42-76,89 and 90* is/are allowed.

6)☒ Claim(s) *77-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7/16/03
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 14, 2004 has been entered.

Status

2. Claims 1-6, 8-25, 27-40, 42-86, 89 and 90 are pending.

Claims 77-86 are rejected.

Claims 1-6, 8-25, 27-40, 42-76, 89 and 90 are allowed.

Any rejection which is not reiterated in this action is hereby withdrawn as no longer applicable.

Claim Rejections - 35 USC § 112

3. As noted in the advisory, the rejection of claims 1-6, 8-21, 74 and 76 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 1-4, 6, 8-23, 25, 27-40, 42-73, 77-86 under 35 U.S.C. 102(a) as being anticipated by Carninci et al (Genome Research (October 2000) 10:1617-1630) is withdrawn in view of the certified English translation of the foreign priority document.

6. Claims 77-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Carninci et al (Genomics (1996) 37:327-336).

Carninci (Genomics) teaches a method of isolating single strand cDNA comprising the steps of treating a hybrid comprising RNA nonspecifically bound to cDNA with RNAse I, which is an enzyme capable of degrading single strand RNA (see page 330, column 2, subheading "RNAse I protection of full length cDNA and figure 1), removing the degraded single stranded RNA (See page 331, column 1, subheading "capture of full length cDNA" and figure 1), and recovering the cDNA (see page 331, column 1, subheading "capture of full length cDNA" and figure 1). Carninci (Genomics) teaches that the resultant cDNA will be full length (See page 330, column 2). Carninci (Genomics) then teaches formation of a library with the full length cDNAs in the Lambda ZAP II vector (see page 331, column 1, especially subheading "Second-strand cDNA synthesis and Cloning). Since the hybridization step is inherently a form of normalization/subtraction, Carninci (Genomics) inherently teaches such a step (see figure 1).

Claim Rejections - 35 USC § 103

7. The rejections under 35 U.S.C. 103(a) are withdrawn in view of the amendment.

Allowable Subject Matter

8. Claims 1-6, 8-25, 27-40, 42-76, 89 and 90 are allowed.

9. The following is a statement of reasons for the indication of allowable subject matter: Claims 1-6, 8-25, 27-40, 42-76, 89 and 90 are indicated as allowed because all of these claims now are drawn to normalization/subtraction methods in which there is a step that removes non-specifically hybridized polynucleotide drivers. The prior art of Chang teaches normalization and subtraction methods, but does not teach specific removal of non-specifically hybridized nucleic acid drivers. While Carninci teaches the use of RNAse to degrade non-hybridized RNA, as in claim 77 which remains rejected, there is no legally sound motivation to combine Carninci with the subtraction/normalization methods of Chang for the purpose of removing the non-specifically hybridized nucleic acid drivers. While these references are combinable to use RNAse to create full length mRNAs, the use of the method to remove non-specifically hybridized nucleic acid drivers represents an unexpected result which overcomes the prima facie case of obviousness that was constructed relying upon reordering of the steps.

Response to Arguments

10. Applicant's arguments filed June 14, 2004 have been fully considered but they are not persuasive.

Applicant then argues the 102(b) over Carninci (1996) by stating that the RNAs being cleaved are not "nonspecifically bound". This argument is not persuasive for same reasons previously given. First, Carninci is performing the same steps as

Applicant for the same purpose with the same enzymes. Consequently, the results must be the same. Second, and more importantly, the RNAs of Carninci which are degraded are, by definition, not specifically bound to DNA or the RNAse enzyme could not degrade them. As Carninci states "mRNA hybridized with full-length CDNA is completely protected from RNase I digestion, but mRNA hybridized to partially synthesized CDNA exposes the single-stranded RNA sequence to attack by RNase I. (see page 330, column 2)." Thus, only unhybridized RNA is cleaved and that unhybridized portion is not specifically bound to any other nucleic acid. Therefore, the teachings of Carninci (1996) meet the current claim limitations.

Applicant concludes by arguing that the limitation is explicit in claim 1. This may be the case, but claim 1 includes many more limitations that claim 77 and was not, nor is, currently under the 102(b) rejection.

Conclusion

11. All rejected claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman

JEFFREY FREDMAN
PRIMARY EXAMINER
7/14/09